February 27, 2001

HOUSE BILL No. 1487

DIGEST OF HB 1487 (Updated February 26, 2001 2:28 PM - DI 77)

Citations Affected: IC 16-41; noncode.

Synopsis: Newborn screening. Expands the newborn screening program, which requires infants to be examined for certain disorders. Requires the state department of health to test for disorders that can be detected by tandem mass spectrometry if money is placed in the newborn screening fund to pay for the test. Prohibits the state department from assessing a fee for a test for disorders that can be detected by tandem mass spectrometry. Allows the state department of health to develop criteria and procedures to determine if a laboratory should conduct tests using tandem mass spectrometry. Requires the state department of health to apply for a federal grant for newborn screening.

Effective: July 1, 2001.

Goeglein, Welch, Day, Budak

January 11, 2001, read first time and referred to Committee on Public Health.
February 8, 2001, amended, reported — Do Pass; referred to Committee on Ways and Means pursuant to House Rule 127.
February 26, 2001, amended, reported — Do Pass.

February 27, 2001

First Regular Session 112th General Assembly (2001)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2000 General Assembly.

HOUSE BILL No. 1487

A BILL FOR AN ACT to amend the Indiana Code concerning health.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 16-41-17-2, AS AMENDED BY P.L.91-1999, SECTION 2, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: Sec. 2. (a) Subject to ~~subsection (c),~~ **subsections (c) and (d),** every infant shall be given examinations at the earliest feasible time for the detection of the following disorders:

(1) Phenylketonuria.

(2) Hypothyroidism.

(3) Hemoglobinopathies, including sickle cell anemia.

(4) Galactosemia.

(5) Maple Syrup urine disease.

(6) Homocystinuria.

(7) Inborn errors of metabolism that result in mental retardation and that are designated by the state department.

(8) Congenital adrenal hyperplasia.

(9) Biotinidase deficiency.

(10) Disorders detected by tandem mass spectrometry, if the state department determines that the technology is available

for use by a designated laboratory under section 7 of this chapter.

(b) Subject to subsection (c), every infant shall be given a physiologic hearing screening examination at the earliest feasible time for the detection of hearing impairments.

(c) If a parent of an infant objects in writing, for reasons pertaining to religious beliefs only, the infant is exempt from the examinations required by this chapter.

(d) The examinations under subsection (a)(10) are not required until the state department determines that there are sufficient funds in the newborn screening fund from appropriations from the general assembly and gifts and grants to the fund for the state department to pay for the cost of the tests performed under subsection (a)(10).

SECTION 2. IC 16-41-17-10 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: Sec. 10. (a) The state department shall develop the following:

(1) A registry for tracking and follow-up of all newborns and individuals for screening.

(2) A centralized program that provides follow-up, diagnosis, management, and family counseling and support, including equipment, supplies, formula, and other materials, for all infants and individuals identified as having one (1) of the disorders listed in section 2 of this chapter.

(3) A laboratory quality assurance program, including proficiency testing.

(4) A statewide network of genetic evaluation and counseling services.

(5) A system for using, for epidemiological survey and research purposes, any waste blood specimen generated under this chapter.

(b) The program described in subsection (a) shall be funded by collection of a newborn screening fee for each newborn screened by a designated laboratory.

(c) The state department shall set the fee and procedures for disbursement under rules adopted under IC 4-22-2. The fee must be based upon the projected cost of the program. **The state department may not assess the part of the fee that is attributable to tests that are performed under section 2(a)(10) of this chapter.** The proposed fee must be approved by the budget agency before the rule is adopted.

(d) The designated laboratory shall assess, collect, and deposit the fees established under subsection (c) in the newborn screening fund established under section 11 of this chapter.

(e) The state department shall annually review:

(1) the newborn screening fee; **and**

(2) the fee assessed by each designated laboratory for testing under section 2(a)(1) through 2(a)(9) of this chapter.

(f) Waste blood specimens used for the purpose of implementing the system described under subsection (a)(5) may not include the name or other identifying characteristics that would identify the individual submitting the specimen.

SECTION 3. IC 16-41-17-11 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: Sec. 11. (a) The newborn screening fund is established for the purpose of carrying out this chapter. The state department shall administer the fund.

(b) The expenses of the newborn screening program shall be paid from money in the fund. **The expenses of performing the tests under section 2(a)(10) of this chapter shall be paid from money in the fund subject to section 2(d) of this chapter.**

(c) Money in the fund at the end of a state fiscal year does not revert to the state general fund.

(d) The fund consists of appropriations from the general assembly, fees assessed under this chapter, and gifts and grants to the fund.

SECTION 4. [EFFECTIVE JULY 1, 2001] **(a) The state department of health shall develop the following:**

(1) Criteria for a laboratory to qualify as a designated laboratory under IC 16-41-17-7 to test for disorders detectable through the use of tandem mass spectrometry under IC 16-41-17-2(a)(10), as amended by this act, and to test for the disorders listed under IC 16-41-17-2(a)(1) through IC 16-41-17-2(a)(9), as amended by this act.

(2) A process for designating one (1) or more qualified laboratories to serve as a designated laboratory under IC 16-41-17-7 to test for disorders detectable through the use of tandem mass spectrometry under IC 16-41-17-2(a)(10), as amended by this act, and to test for the disorders listed under IC 16-41-17-2(a)(1) through IC 16-41-17-2(a)(9), as amended by this act.

(b) Except as provided in subsection (c), after the state department of health has developed the qualifying criteria in subsection (a)(1) and the designating processes in subsection (a)(2), the state department of health may designate one (1) or more qualified laboratories under IC 16-42-17-7 to test for disorders detectable through the use of tandem mass spectrometry under

IC 16-41-17-2(a)(10), as amended by this act, and to test for the disorders listed under IC 16-41-17-2(a)(1) through IC 16-41-17-2(a)(9), as amended by this act. A designated laboratory may use tandem mass spectrometry to test for those disorders listed under IC 16-41-17-2(a)(1) through IC 16-41-17-2(a)(9), as amended by this act, that are detectable through the use of tandem mass spectrometry.

(c) The state department of health may not designate a laboratory to test for disorders detectable through the use of tandem mass spectrometry under IC 16-41-17-2(a)(10), as amended by this act, until funds have been received by the state department of health to pay for the tests under IC 16-41-17-2(a)(10), as amended by this act.

(d) The state department of health shall apply for a grant through the federal Public Health Service Act and any other federal grants available to expand or improve programs to provide screening, testing, or other specialty services for newborns or children at risk of disorders detectable through the use of tandem mass spectrometry.

(e) This SECTION expires July 1, 2006.

COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred House Bill 1487, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill be amended as follows:

Page 1, between the enacting clause and line 1, begin a new paragraph and insert:

"SECTION 1. IC 12-15-15-6 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: **Sec. 6. (a) Except as provided in subsection (b), the office shall pay for a hospital's collection, handling, and delivery of a newborn blood specimen for testing under IC 16-41-17-2(a)(10). Payment to a hospital must be in an amount equal to:**

(1) the costs incurred by the hospital to collect, handle, and deliver the newborn blood specimen obtained for testing under IC 16-41-17-2(a)(10);

(2) any fee assessed against the hospital for a laboratory's testing of the blood specimen under IC 16-41-17-2(a)(10); and

(3) any fee assessed against the hospital by the state department of health against the hospital in connection with testing of the blood specimen under IC 16-41-17-2(a)(10).

(b) The costs under subsection (a)(1) may not include costs that are also attributable to a hospital's collection, handling, and delivery of a newborn blood specimen obtained for testing under IC 16-41-17-2(a)(1) through IC 16-41-17-2(a)(9).

Page 1, line 12, delete "significant medical".

Page 1, line 13, delete "illness, death, or".

Page 1, between lines 14 and 15, begin a new line block indented and insert:

"**(8) Congenital adrenal hyperplasia.**

(9) Biotinidase deficiency.

(10) Disorders detected by tandem mass spectrometry, if the state department determines that the technology is available for use by a designated laboratory under section 7 of this chapter.".

Page 2, after line 3, begin a new paragraph and insert:

"SECTION 3. IC 16-41-17-10 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: Sec. 10. (a) The state department shall develop the following:

(1) A registry for tracking and follow-up of all newborns and individuals for screening.

(2) A centralized program that provides follow-up, diagnosis,

management, and family counseling and support, including equipment, supplies, formula, and other materials, for all infants and individuals identified as having one (1) of the disorders listed in section 2 of this chapter.

(3) A laboratory quality assurance program, including proficiency testing.

(4) A statewide network of genetic evaluation and counseling services.

(5) A system for using, for epidemiological survey and research purposes, any waste blood specimen generated under this chapter.

(b) The program described in subsection (a) shall be funded by collection of a newborn screening fee for each newborn screened by a designated laboratory.

(c) The state department shall set the fee and procedures for disbursement under rules adopted under IC 4-22-2. The fee must be based upon the projected cost of the program. **The state department shall identify the part of the fee that is attributable to tests that are performed under section 2(a)(10) of this chapter.** The proposed fee must be approved by the budget agency before the rule is adopted.

(d) The designated laboratory shall assess, collect, and deposit the fees established under subsection (c) in the newborn screening fund established under section 11 of this chapter.

(e) The state department shall annually review:

(1) the newborn screening fee;

(2) the fee assessed by each designated laboratory under section 10.5 of this chapter; and

(3) the fee assessed by each designated laboratory for testing under section 2(a)(1) through section 2(a)(9) of this chapter.

(f) Waste blood specimens used for the purpose of implementing the system described under subsection (a)(5) may not include the name or other identifying characteristics that would identify the individual submitting the specimen.

SECTION 4. IC 16-41-17-10.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: **Sec. 10.5. (a) Separate from any fee a designated laboratory may assess for tests performed under section 2(a)(1) through section 2(a)(9) of this chapter, a designated laboratory shall assess a fee for each newborn screened by the laboratory that:**

(1) covers the cost incurred by the laboratory in performing a screen under section 2(a)(10) of this chapter; and

(2) funds the laboratory's purchase or lease of tandem mass

spectrometry technology pro rated over a period of time determined to be reasonable by the state department.

(b) A designated laboratory shall assess the fee referenced in subsection (a) separately from the fee the laboratory assesses for testing under section 2(a)(1) through section 2(a)(9) of this chapter and from the newborn screening fee the laboratory assesses under section 10(d) of this chapter.

(c) The amount of the fee assessed under subsection (a) must be approved by the state department.

(d) If a designated laboratory uses tandem mass spectrometry to test for one (1) or more disorders listed under section 2(a)(1) through section 2(a)(9), the laboratory shall reduce the fee the laboratory assesses under section 2(a)(1) through section 2(a)(9) of this chapter.

(e) Except as provided in subsection (f), the portion of a laboratory's fee attributable to the funding of the laboratory's purchase or lease of tandem mass spectrometry technology must be eliminated once the purchase or lease has been paid for.

(f) After the purchase or lease of tandem mass spectrometry technology has been paid for, that portion of a laboratory's fee attributable to the funding of the laboratory's purchase or lease of tandem mass spectrometry technology may be maintained or adjusted, as determined by the state department, for purposes of funding the laboratory's purchase or lease of new tandem mass spectrometry technology.

SECTION 5. [EFFECTIVE JULY 1, 2001] **(a) The state department of health shall develop the following:**

(1) Develop criteria for a laboratory to qualify as a designated laboratory under IC 16-41-17-7 to test for disorders detectable through the use of tandem mass spectrometry under IC 16-41-17-2(a)(10), as amended by this act, and to test for the disorders listed under IC 16-41-17-2(a)(1) through IC 16-41-17-2(a)(9), as amended by this act.

(2) Develop a process for designating one (1) or more qualified laboratories to serve as a designated laboratory under IC 16-41-17-7 to test for disorders detectable through the use of tandem mass spectrometry under IC 16-41-17-2(a)(10), as amended by this act, and to test for the disorders listed under IC 16-41-17-2(a)(1) through IC 16-41-17-2(a)(9), as amended by this act.

(b) After the state department of health has developed the qualifying criteria in subsection (a)(1) and the designating

processes in subsection (a)(2), the state department of health may, in its discretion, designate one (1) or more qualified laboratories under IC 16-42-17-7 to test for disorders detectable through the use of tandem mass spectrometry under IC 16-41-17-2(a)(10), as amended by this act, and to test for the disorders listed under IC 16-41-17-2(a)(1) through IC 16-41-17-2(a)(9), as amended by this act. A designated laboratory may use tandem mass spectrometry to test for those disorders listed under IC 16-41-17-2(a)(1) through IC 16-41-17-2(a)(9), as amended by this act that are detectable through the use of tandem mass spectrometry.

(c) This SECTION expires July 1, 2006.".

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to HB 1487 as introduced.)

BROWN C, Chair

Committee Vote: yeas 13, nays 0.

COMMITTEE REPORT

Mr. Speaker: Your Committee on Ways and Means, to which was referred House Bill 1487, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill be amended as follows:

Delete the committee report of the Public Health Committee adopted February 8, 2001.

Page 1, line 3, strike "subsection (c)," and insert "**subsections (c) and (d),**".

Page 1, line 12, delete "significant medical".

Page 1, line 13, delete "illness, death, or".

Page 1, between lines 14 and 15, begin a new line block indented and insert:

"**(8) Congenital adrenal hyperplasia.**

(9) Biotinidase deficiency.

(10) Disorders detected by tandem mass spectrometry, if the state department determines that the technology is available for use by a designated laboratory under section 7 of this chapter.".

Page 2, after line 3, begin a new paragraph and insert:

"**(d) The examinations under subsection (a)(10) are not required until the state department determines that there are sufficient funds in the newborn screening fund from appropriations from the general assembly and gifts and grants to the fund for the state department to pay for the cost of the tests performed under subsection (a)(10).**

SECTION 2. IC 16-41-17-10 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: Sec. 10. (a) The state department shall develop the following:

(1) A registry for tracking and follow-up of all newborns and individuals for screening.

(2) A centralized program that provides follow-up, diagnosis, management, and family counseling and support, including equipment, supplies, formula, and other materials, for all infants and individuals identified as having one (1) of the disorders listed in section 2 of this chapter.

(3) A laboratory quality assurance program, including proficiency testing.

(4) A statewide network of genetic evaluation and counseling services.

(5) A system for using, for epidemiological survey and research purposes, any waste blood specimen generated under this chapter.

(b) The program described in subsection (a) shall be funded by collection of a newborn screening fee for each newborn screened by a designated laboratory.

(c) The state department shall set the fee and procedures for disbursement under rules adopted under IC 4-22-2. The fee must be based upon the projected cost of the program. **The state department may not assess the part of the fee that is attributable to tests that are performed under section 2(a)(10) of this chapter.** The proposed fee must be approved by the budget agency before the rule is adopted.

(d) The designated laboratory shall assess, collect, and deposit the fees established under subsection (c) in the newborn screening fund established under section 11 of this chapter.

(e) The state department shall annually review:

(1) the newborn screening fee; **and**

(2) the fee assessed by each designated laboratory for testing under section 2(a)(1) through 2(a)(9) of this chapter.

(f) Waste blood specimens used for the purpose of implementing the system described under subsection (a)(5) may not include the name or other identifying characteristics that would identify the individual submitting the specimen.

SECTION 3. IC 16-41-17-11 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: Sec. 11. (a) The newborn screening fund is established for the purpose of carrying out this chapter. The state department shall administer the fund.

(b) The expenses of the newborn screening program shall be paid from money in the fund. **The expenses of performing the tests under section 2(a)(10) of this chapter shall be paid from money in the fund subject to section 2(d) of this chapter.**

(c) Money in the fund at the end of a state fiscal year does not revert to the state general fund.

(d) The fund consists of appropriations from the general assembly, fees assessed under this chapter, and gifts and grants to the fund.

SECTION 4. [EFFECTIVE JULY 1, 2001] **(a) The state department of health shall develop the following:**

(1) Criteria for a laboratory to qualify as a designated laboratory under IC 16-41-17-7 to test for disorders detectable through the use of tandem mass spectrometry under IC 16-41-17-2(a)(10), as amended by this act, and to test for the disorders listed under IC 16-41-17-2(a)(1) through IC 16-41-17-2(a)(9), as amended by this act.

(2) A process for designating one (1) or more qualified

laboratories to serve as a designated laboratory under IC 16-41-17-7 to test for disorders detectable through the use of tandem mass spectrometry under IC 16-41-17-2(a)(10), as amended by this act, and to test for the disorders listed under IC 16-41-17-2(a)(1) through IC 16-41-17-2(a)(9), as amended by this act.

(b) Except as provided in subsection (c), after the state department of health has developed the qualifying criteria in subsection (a)(1) and the designating processes in subsection (a)(2), the state department of health may designate one (1) or more qualified laboratories under IC 16-42-17-7 to test for disorders detectable through the use of tandem mass spectrometry under IC 16-41-17-2(a)(10), as amended by this act, and to test for the disorders listed under IC 16-41-17-2(a)(1) through IC 16-41-17-2(a)(9), as amended by this act. A designated laboratory may use tandem mass spectrometry to test for those disorders listed under IC 16-41-17-2(a)(1) through IC 16-41-17-2(a)(9), as amended by this act, that are detectable through the use of tandem mass spectrometry.

(c) The state department of health may not designate a laboratory to test for disorders detectable through the use of tandem mass spectrometry under IC 16-41-17-2(a)(10), as amended by this act, until funds have been received by the state department of health to pay for the tests under IC 16-41-17-2(a)(10), as amended by this act.

(d) The state department of health shall apply for a grant through the federal Public Health Service Act and any other federal grants available to expand or improve programs to provide screening, testing, or other specialty services for newborns or children at risk of disorders detectable through the use of tandem mass spectrometry.

(e) This SECTION expires July 1, 2006.".

and when so amended that said bill do pass.

(Reference is to HB 1487 as introduced, and as amended by the committee report of the Public Health Committee on February 8, 2001.)

BAUER, Chair

Committee Vote: yeas 26, nays 0.